

SEP 8 1995

Dr. Frank Serdy
Regulatory Affairs Director
The Agricultural Group of
Monsanto Company
700 Chesterfield Parkway North
Chesterfield, MO 63198

Dear Dr. Serdy:

This is in regard to Monsanto's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its Roundup Ready™ cotton lines 1445 and 1698 which are genetically modified to be tolerant to the herbicide glyphosate. The new cotton varieties have been rendered tolerant to the herbicide glyphosate by the expression of the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene isolated from *Agrobacterium* sp. strain CP4.

On April 13, 1995, Monsanto submitted summary information to support its safety and nutritional assessment of cotton lines 1445 and 1698. This communication informed FDA of the steps taken by Monsanto to ensure that these products comply with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that these new cotton varieties are not materially different in composition, safety, or any other relevant parameter from cotton varieties currently on the market and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in file BNF 0026 which will be maintained in the Office of Premarket Approval.

Page 2 - Dr. Frank Serdy

Based on the information Monsanto has presented, FDA has no additional questions concerning these products at this time. However, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition